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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,409

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207,561

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EXAMINER

SCHLENTZ, NATHAN W

ART UNIT

PAPER NUMBER

1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,409	Applicant(s) PICCOLO ET AL.	
	Examiner Nathan W. Schlientz	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-9, in the reply filed on 15 December 2009 is acknowledged. The traversal is on the ground(s) that claim 1 relates to a complex with cyclodextrin, wherein both the synergist compound and the insecticide and/or insect growth regulator are included. This is not found persuasive because claim 1 recites, "said composition *being obtainable by* subjecting both components (i) and (ii) to simultaneous complexing with cyclodextrin." The term "being obtainable by" is merely one method by which the composition can be made, and does not limit the claim to simultaneously complexing both components (i) and (ii) with cyclodextrin. It is noted that the claim is not necessarily a product-by-process claim (See MPEP 2113) because the claim does not state that the product *is obtained by* the recited method, but merely that it is possible to obtain the product by that method. Therefore, claim 1 is being construed by the examiner as merely a composition comprising components (i) and (ii). With respect to claims 2-4 and 6, the examiner is construing these claims to also comprise a cyclodextrin. Again, however, it is not necessary for both components (i) and (ii) to be simultaneously complexed with said cyclodextrin. Claims 10, 11, 14 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-11, 14 and 15 are pending in the present application. Claims 10, 11, 14 and 15 are withdrawn, as discussed above. Therefore, claims 1-9 are examined herein on the merits for patentability. No claim is allowed at this time.

Claim amendments

It is noted that Applicants filed an amendment to the claims on 25 April 2006 wherein all deletions were encompassed within single brackets. It is required that future amendments comply with 37 CFR 1.121(c)(2), reproduced herein.

When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. ***The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.*** Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn— currently amended."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites, "Composition as claimed in claim 1... *possibly* dissolved/emulsified in water or in aqueous solutions of water miscible

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solvents.” However, it is not clear if the composition according to claim is or is not dissolved/emulsified in water or in aqueous solutions of water miscible solvents. The term *possibly* indicates that it could be dissolved/emulsified, but it does not necessarily have to be. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Biebel et al. (International Journal of Pharmaceutics, 2003).

Biebel et al. disclose that pyrethrum extract is an ideal pesticide, but it has low light stability (Abstract; and pg. 175, Introduction). This drawback can be overcome by the complexation of pyrethrum extract with γ -cyclodextrin (Abstract; pg. 176, sentence bridging the left and right columns; and section 2.2.1). Biebel et al. further disclose that pyrethrins, such as pyrethrum extract, experience rapid metabolism which is a drawback concerning the frequency of application. Therefore, synergists are added to ensure an insecticidal effect of pyrethrum, wherein the most widely used synergist in the last decades has been piperonyl butoxide (PBO) (pg. 175, right column, ln. 2-12). Biebel et al. disclose that synergists may also profit from a complexation with cyclodextrins, and thus sesamol was also complexed with γ -cyclodextrin (pg. 176, right

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column, ln. 2-7; and section 2.2.2). Biebel et al. disclose compositions comprising a 10 to 50 fold excess synergist compared to pyrethrum (Table 1).

2. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mifune et al. (US 3,846,551).

Mifune et al. disclose compositions comprising a pyrethroid with a cyclodextrin which contributes to the improvement of the stability of the pyrethroids to heat and light and exhibits insecticidal and acaricidal effects (col. 1, ln. 4-10). Mifune et al. further disclose that the cyclodextrins available are α -cyclodextrin, β -cyclodextrin, and γ -cyclodextrin (col. 3, ln. 52-59). Mifune et al. disclose that the active ingredient can be formed by contacting at least one pyrethroid intimately with at least one cyclodextrin in the presence of water, it will be readily understood that depending upon the formulation, the interacted product can be formed at the time of preparing the final pesticidal composition instead of preparing the interacted product in advance and then blending it with a diluent or carrier. For instance, in the case of a wettable powder, the interacted product can be formed during its preparation (col. 5, ln. 27-37).

The insecticidal and acaricidal composition of Mifune et al. may be in various formulations, such as a liquid, emulsifiable concentrate, wettable powder, oil, aerosol, paste, fumigant, dust, granule, tablet, or pellet (col. 5, ln. 38-41). The insecticidal and acaricidal composition contains various gaseous, liquid or solid diluents or carriers, and if desired, may be further contain various assistants, such as a surface active agent, emulsifier, dispersing agent, spreader, sticker, synergist, antioxidant, ultraviolet

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absorbent, and other insecticide (col. 5, ln. 43-49), wherein examples of the synergist include piperonyl butoxide (col. 6, ln. 32).

Mifune et al. further disclose examples wherein a pyrethroid, cyclodextrin and piperonyl butoxide are well kneaded to form a paste (Formulation Example 7). Cyclodextrin complexes are known to form by kneading with other components, such as pyrethroids and synergists (col. 4, ln. 1-19). The proportions of the pyrethroid to the cyclodextrin in the resulting complex may vary over a range of 0.5 to 1.5 mols per mol of the cyclodextrin (col. 4, ln. 26-29). Therefore, the compositions according to Formulation Example 7 would comprise both the pyrethroid and the synergist complexed with cyclodextrin since they were well kneaded in the presence of cyclodextrin in water.

3. Claims 1, 2, 5, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Szejtli et al. (US 4,524,068).

Szejtli et al. disclose inclusion complexes of piperonyl butoxide (PBO) formed with cyclodextrin wherein the complexes synergize the pesticidal effect of known insecticides and fungicides to a much higher extent than PBO used per se (Abstract). PBO is generally used to synergize pyrethrins and synthetic pyrethroids and organic phosphate compositions (col. 1, ln. 34-36). It is known that the active ingredients of drugs and pesticides can be included into cyclodextrins and the inclusion complexes thus obtained can influence and modify the biological characteristics thereof (col. 1, ln. 59-62). It has been found that the solubility of PBO and other similar synergistic agents

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can be increased by forming a cyclodextrin complex. The inclusion complex goes into solution more rapidly and thereby the velocity of penetration through the biological membrane is increased as well. The absolute activity of the synergistic component becomes higher and therefore in an identical active ingredient concentration the biological effect is exhibited more promptly and stronger or the same biological effect can be reached by using a lower active ingredient concentration (col. 1, ln. 64 through col. 2, ln. 6).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616